

Exhibit A

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

**IN RE: XARELTO (RIVAROXABAN) PRODUCTS
LIABILITY LITIGATION**

*** MDL NO. 2592**

*** SECTION L**

*** JUDGE ELDON E. FALLON**

*** MAG. JUDGE NORTH**

THIS DOCUMENT RELATES TO:

14-2720 Boudreaux

ORDER AND REASONS

Before the Court are various Motions in Limine filed by Plaintiffs Joseph Boudreaux and Sharyn Orr (collectively, “Plaintiffs”), and by Defendants Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho LLC, Johnson & Johnson, Bayer Pharma AG, and Bayer Healthcare Pharmaceuticals Inc. (collectively, “Defendants”). All of the motions are opposed. Having considered the parties’ briefs and the applicable law, the Court now issues this order and reasons.

1) Plaintiffs’ Motion in Limine to Regarding the Relationship Between Plaintiff and His Attorneys [R. Doc. 5919]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about, the relationship between Plaintiffs and their attorneys, including how, when, why or under what circumstances Plaintiff chose or employed any of their attorneys. More specifically, Plaintiffs seek to exclude any evidence or argument relating to any television commercials or other advertisements he saw about litigation involving patients who suffered from bleeding events after taking Xarelto, or the timing of his retention of counsel in relation to seeing such commercials or advertisements. Defendants oppose the motion.

Pursuant to Federal Rule of Evidence 401, the Court **SUSTAINS** this motion.

2) Plaintiffs' Motion in Limine No. 7 Regarding Hearsay Statements From Medical Associations [R. Doc. 5920]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about, hearsay statements from medical associations, specifically "position statements." Defendants oppose the motion.

Under Rule 802 of the Federal Rules of Evidence, hearsay is inadmissible unless allowable under one of the exceptions specified in the Federal Rules of Evidence or a federal statute. *See* FED. R. EVID. 801, 802, 803. The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial, at which time the parties may argue the applicability of the hearsay rule and its exceptions.

3) Plaintiff's Motion in Limine No. 8 Regarding Plaintiffs' Counsels' Advertisements [R. Doc. 5921]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about, Plaintiffs' counsels' advertisements. More specifically, Plaintiff requests an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about:

(1) Plaintiffs' counsel's advertisements, websites, public appearances, or other representations related to Xarelto; or (2) whether Plaintiffs' counsels' advertisements, websites, public appearances, or other representations may have caused a spike in adverse events and/or adverse event reporting related to Xarelto. Defendants oppose the motion.

This Court holds that Plaintiff's motion is **SUSTAINED**, unless the information becomes relevant to the actions or inactions of the specific Plaintiff. For example, if the specific Plaintiff used or refrain from using Xarelto due to the advertisement and an injury resulted.

4) Plaintiffs' Motion in Limine No. 9 Regarding Plaintiffs' Counsels' Communications Or Meetings With Mr. Boudreaux's Prescribing Or Treating Physicians [Rec. Doc. 5922]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about, Plaintiffs' counsels' communications or meetings with Mr. Boudreaux's prescribing or treating physicians. Plaintiffs anticipate that Defendants may attempt to present evidence of ex parte communications between Plaintiffs' counsel and Mr. Boudreaux's prescribing or treating physicians, suggesting that Plaintiffs' counsel may have influenced the physicians' testimony. Defendants oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial if it becomes relevant to the credibility of the witness.

5) Plaintiffs' Motion in Limine No. 10 Regarding an Alleged "Litigation Crisis" "Lawsuit Crisis," "Lawsuit Abuse," or "Lawyer-Driven Litigation" [R. Doc. 5923]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about, an Alleged "Litigation Crisis," "Lawsuit Crisis," "Lawsuit Abuse" or "Lawyer-Driven Litigation." Plaintiffs suggest that Defendants may attempt to present argument or evidence suggesting that this lawsuit or the Xarelto litigation as a whole is lawyer-driven, fabricated or exaggerated by counsel who make money through product liability lawsuits. Defendants oppose the motion.

Pursuant to Federal Rules of Evidence 401 and 403, the Court **SUSTAINS** this motion.

6) Plaintiffs' Motion in Limine No. 11 Regarding Personal Use of Xarelto [R. Doc. 5924]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about, the personal use of Xarelto by any party's family members, employees, experts, or witnesses. Defendants oppose the motion.

The Court **SUSTAINS** this motion, except with regards to witnesses and experts, in which case the court **RESERVES** ruling until trial, as the issue may go to credibility.

7) Plaintiffs' Motion in Limine No. 12 Regarding Individual Character Evidence [R. Doc. 5925]

Plaintiffs move for an order prohibiting all witnesses and counsel from making comments or references, or attempting to introduce or introducing testimony or evidence, to bolster the unchallenged character (e.g., honesty) or traits (e.g., generosity) of Defendants' current or former employees, managers, consultants, experts, agents, fiduciaries, or witnesses, but noting that bolstering character or trait evidence about those individuals may be presented if, but only if, their character or traits have been challenged. Defendants oppose the motion.

Pursuant to Federal Rules of Evidence 401, 403, and 608(a), the Court **SUSTAINS** this motion.

8) Plaintiffs' Motion in Limine No. 13 Regarding Defendants' Corporate Character and Good Acts [R. Doc. 5926]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about, Defendants' corporate character, reputation, good acts, or charitable contributions, or the societal good performed by their manufacture of pharmaceuticals.

Alternatively, if Defendants are permitted to introduce evidence of their "good" character, then

Plaintiffs should be permitted to offer evidence of Defendants' "bad" character. Defendants oppose the motion.

Pursuant to Federal Rules of Evidence 401 and 404, the Court **SUSTAINS** this motion.

9) Plaintiffs' Motion in Limine No. 14 Regarding Preemption and State Tort Laws [R. Doc. 5927]

Plaintiffs have moved for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence, or introducing testimony or evidence, suggesting that state law should be preempted by federal law, or that Defendants should not be subjected to fifty-one separate tort law regimes. Defendants oppose the motion.

This motion seeks to prohibit testimony, evidence, and commentary regarding a question of law that is not appropriate for consideration by the finder of fact. Accordingly, the Court **SUSTAINS** this motion.

10) Plaintiffs' Motion in Limine No. 15 Regarding FDA Approval [R. Doc. 5928]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence, or introducing testimony or evidence, suggesting that the FDA's approval of Xarelto or Defendants' compliance with FDA regulations absolves Defendants of liability or establishes that Xarelto is "safe and effective." Such evidence is irrelevant, and any probative value would be greatly outweighed by the dangers of unfair prejudice, confusion of the issues, misleading the jury, undue delay and a waste of time.

Defendants oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

11) Plaintiffs' Motion in Limine No. 16 Regarding The Effect of State Tort Laws [R. Doc. 5929]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence, or introducing testimony or evidence, suggesting that state tort laws undercut the FDA's mission to provide only scientifically valid warnings, or frustrate the FDA's protective regime, or pressure drug manufacturers to add unsubstantiated, false or invalid warnings in order to avoid lawsuits. Defendants oppose the motion.

Pursuant to Federal Rule of Evidence 403, the Court **SUSTAINS** this motion.

12) Plaintiffs' Motion in Limine No. 17 Regarding Potential Adverse Effects of a Plaintiffs' Verdict [R. Doc. 5930]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence, or introducing testimony or evidence, suggesting that a verdict for Plaintiffs could have any potential adverse effects. This includes, but is not limited to, suggestions about a verdict's potential effect on the pharmaceutical industry, manufacturers' incentive or ability to develop drugs, the ability of doctors to choose which drugs to prescribe for their patients, insurance rates or premiums, drug costs, the ability to purchase drugs, the economy, Defendants' finances or stock values, Defendants' ability to compete, layoffs or lost jobs. Defendants oppose the motion.

Pursuant to Federal Rules of Evidence 401 and 403, the Court **SUSTAINS** this motion.

13) Plaintiffs' Motion in Limine No. 19 Regarding FDA Approval [R. Doc. 5931]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence, or introducing testimony or evidence, suggesting that the FDA invited drug manufactures, including Defendants, to develop anticoagulants. Such evidence is irrelevant, and any probative value would be greatly

outweighed by the dangers of unfair prejudice, confusion of the issues, misleading the jury, undue delay and a waste of time. Defendants oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

14) Defendants' Motion in Limine to Exclude Evidence and Argument Regarding Marketing, Advertising, or Promotional Materials Not Relied on By Plaintiff's Prescribing Physician (Defendants' Joint Motion in Limine No. 2) [R. Doc. 5933]

Defendants move to preclude Plaintiffs from presenting evidence and argument regarding marketing, advertising, or promotional materials not relied on by Dr. Kenneth Wong, Joseph Boudreaux, Jr.'s prescribing physician, in deciding to prescribe Xarelto. They argue there is no evidence that Dr. Wong relied on any marketing, advertising, or promotional materials in making his prescribing decision, and therefore these materials are irrelevant to Plaintiffs' claims under the Louisiana Product Liability Act ("LPLA"). Moreover, introduction of these materials at trial would only cause Defendants undue prejudice, confuse the issues, mislead the jury, and waste time on collateral matters that would not inform any question that the jury will be asked to decide. Plaintiffs oppose the motion.

Pursuant to Federal Rules of Evidence 401 and 403, the Court **SUSTAINS** this motion, unless evidence indicates that Plaintiffs themselves saw the marketing material, were motivated by that material to request Xarelto from their treating physicians, and did request Xarelto from their treating physicians.

15) Defendants' Motion in Limine to Exclude Evidence and Argument Regarding the September 2015 Xarelto Label And/Or Related Correspondence (Defendants' Joint Motion in Limine No. 8) [R. Doc. 5935]

Defendants move to exclude evidence and argument related to the September 2015 Xarelto® label and/or related correspondence. That label was not in effect at the time that Joseph Boudreaux, Jr., was prescribed Xarelto in January and February 2014, is not a label that would

have changed Mr. Boudreaux's prescribing physician's decision to prescribe Xarelto to Mr. Boudreaux, and constitutes an inadmissible subsequent remedial measure under Federal Rule of Evidence 407. Plaintiffs oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

16) Defendants' Motion in Limine to Exclude Dr. Cuculich and Dr. Smart's Testimony Regarding Defendants' Detail Representatives (Defendants Joint Motion in Limine No. 10) [R. Doc. 5937]

Defendants move to exclude the testimony of Dr. Phillip Cuculich and Dr. Frank Smart regarding their opinions about Defendants' marketing practices and their personal experiences with Defendants' detail representatives. Defendants anticipate that Plaintiffs may attempt to introduce testimony about what Dr. Smart and Dr. Cuculich allegedly were told by detail representatives, almost all of whom they have not identified, in order to suggest that Defendants engaged in deceptive marketing practices. Defendants contend that such testimony about what unidentified detail representatives said is hearsay and should be barred. Nor is it relevant to any issue that the jury will be asked to decide, as neither of these experts treated or made prescribing decisions for Joseph Boudreaux, Jr. And further, any remote probative value their testimony might have would be substantially outweighed by the risk of unfair prejudice and jury confusion. Plaintiffs oppose the motion.

The Court **SUSTAINS** this motion, unless the testimony is connected to the facts of the case being tried.

17) Defendants' Motion in Limine to Exclude Evidence or Argument that the Xarelto Label Should Have Included Information About the INRatio Device Recall Used in ROCKET AF or that is Inconsistent with FDA's September 2016

Reanalysis that the Recall Did Not Impact the results of Rocket AF [R.Doc. 5940]

Defendants move to exclude any and all evidence and argument (1) that Defendants “defrauded the FDA,” (2) that Defendants should have included information in the Xarelto label about the recall of the INRatio device used in the clinical trial ROCKET AF or reported the recall earlier, or (3) that is inconsistent with FDA’s extensive and comprehensive review of the impact of the recall on ROCKET AF, issued in September 2016 and entitled “Impact of use of the INRatio® device in ROCKET AF.” Plaintiffs oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

18) Defendants’ Motion in Limine to Exclude Evidence and Argument Related to Use of Xarelto for Treatment of Acute Coronary Syndrome (Defendants’ Joint Motion in Limine No. 5) [R. Doc. 5942]

Defendants move to exclude all evidence and argument related to the use of Xarelto for the treatment of Acute Coronary Syndrome (“ACS”), a medical syndrome associated with sudden, reduced blood flow to the heart. Mr. Boudreaux was not diagnosed with ACS. Instead, Mr. Boudreaux was diagnosed with atrial fibrillation, a separate and distinct medical condition, and was prescribed Xarelto to reduce the risk of stroke and embolism associated with that condition. As such, any evidence related to ACS—and Defendants’ attempts to seek approval from the FDA for the use of Xarelto to treat ACS—is not relevant, and any perceived probative value that Plaintiffs may attach to such evidence is substantially outweighed by its potential to unduly prejudice Defendants, confuse the issues, and cause delay. Plaintiffs oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

19) Plaintiffs' Motion in Limine (No. 22) Regarding Defendants' Lack of Permission to Change the Label of Xarelto Without Prior FDA Approval [R. Doc. 5943]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence, or introducing testimony or evidence that Defendants were not permitted to change the label for Xarelto without prior FDA approval. Any such evidence must be excluded as irrelevant, unduly prejudicial, and confusing to the jury because FDA regulations and clear Supreme Court precedent establish that such evidence is false. Therefore, Plaintiff submits that such evidence should be excluded and Defendants should be precluded from offering any such evidence, testimony, comment, inference and/or document at the time of trial. Defendants oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

20) Plaintiffs' Motion in Limine (No. 23) Regarding Diluted Warnings [R. Doc. 5944]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about, the alleged potential for too many warnings of serious injuries to dilute the general effectiveness of warnings. Defendants oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

21) Plaintiffs' Motion in Limine (No. 26) Regarding Compensation of Dr. Kessler [R. Doc. 5946]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, introducing testimony or evidence, attempting to elicit testimony of, or arguing, the following matters in the presence of the jury, whether directly or indirectly, and whether at *voir dire* or during trial: (A) Any argument or reference to the compensation arrangement of David A.

Kessler, M.D. with the University of California regarding the California Health Services Compensation Plan; or (B) Any argument or reference to Dr. Kessler's spending, billing and/or expenses as FDA Commissioner. Plaintiffs argue this evidence is not related in any way to whether Xarelto is a defective product, whether the warnings provided about Xarelto were adequate, or whether Defendants acted negligently. It will have no tendency to make a fact that is of consequence in this action more or less probable than it would be without the evidence. Defendants oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

22) Defendants' Motion in Limine to Exclude Argument or Evidence Regarding the Lack of a Reversal Agent for Xarelto (Defendants' Joint Motion in Limine No. 6) [R. Doc. 5947]

Defendants move to preclude Plaintiffs from presenting any evidence or argument regarding the lack of a reversal agent (or "antidote") for Xarelto. They argue that Plaintiffs' experts have testified that a reversal agent "would have served no purpose" for Mr. Boudreaux and accordingly have abandoned their claim that a reversal agent would have made Xarelto safer, and any evidence or argument regarding the lack of such a reversal agent is irrelevant, and would be unduly prejudicial, confuse the issues, and waste trial time. Plaintiffs oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

23) Plaintiffs' Motion in Limine to Exclude Argument or Evidence Regarding the Lack of a Reversal Agent for Xarelto (Defendants' Joint Motion in Limine No. 6) [R. Doc. 5949]

Plaintiffs have moved for an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about how Xarelto has saved lives by preventing strokes. Alternatively, if

Defendants are permitted to introduce evidence of Xarelto's life-saving abilities, then Plaintiffs should be permitted to offer evidence of the numerous pending lawsuits filed as a result of those injured by taking Xarelto. Defendants oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

24) Defendants' Motion in Limine to Exclude Evidence of Dr. Califf's Proposal to Pursue "Rocket 2.0" Under Federal Rules of Evidence 402 & 403 (Defendants' Joint Motion in Limine No. 9) [R. Doc. 5950]

Defendants move to exclude any evidence of or reference to non-party Dr. Robert Califf's out-of-court statements communicating his musings and ideas that it would be interesting to consider a clinical trial to test a dose or dosing regimen for Xarelto different than that approved by FDA. Defendants argue that these emails—and any other evidence or testimony based on them—are irrelevant because Plaintiffs have conceded, consistent with Louisiana law, that "the failure to test theory is not being presented by Mr. Boudreaux," and Plaintiffs have renounced any dosing-related claim. Plaintiffs oppose the motion.

This evidence is likely excludable under Federal Rules of Evidence 401 and 403, but the Court will **RESERVE** ruling until trial to see the context in which the matter is introduced.

25) Plaintiffs' Motion in Limine Regarding References to Advertising or Choice of Counsel [R. Doc. 5951]

Plaintiffs request an order prohibiting all witnesses and counsel from commenting on, referring to, attempting to introduce testimony or evidence about, or introducing testimony or evidence about Plaintiffs' choice of Counsel, including any related advertisements, websites, public appearances, or other representations related to Xarelto. Plaintiffs argue that their choice of counsel, including why or how counsel was retained, are not matters relevant to the trial of this matter, as choice of counsel and any advertising done by Plaintiffs' counsel have absolutely no bearing on the liability or damages issues before this Court. The prejudice and confusion

arising from those matters being discussed or referred to at trial far outweighs any speculative probative value of their introduction. Defendants oppose the motion.

The Court will **SUSTAIN** this motion.

26) Plaintiffs' Motion in Limine Regarding Mr. Joseph Boudreaux's Other Prescriptions [R. Doc. 5952]

Plaintiffs move for an order prohibiting all witnesses and counsel from commenting on, referring to, introducing testimony or evidence about, attempting to elicit testimony about, or arguing, the following matters in the presence of the jury, whether directly or indirectly, and whether at *voir dire* or during trial: (A) Mr. Joseph Boudreaux's Indocin prescription, which had been prescribed, but was not taken during the time period when he suffered his major bleed; and (B) Mr. Boudreaux's Metformin prescription, which he was taking at the time of his gastrointestinal bleed, but is not suggestive of contributing to his major bleed. Defendants oppose the motion.

Because context may be important in this matter, the Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

27) Defendants' Motion in Limine to Exclude Evidence of Foreign Labeling and Regulatory Actions Under Federal Rules of Evidence 402 and 403 [R. Doc. 5954]

Defendants move to exclude evidence of foreign labeling and regulatory actions. Defendants argue that because those unique foreign regulatory standards and the bases for regulatory action in each jurisdiction differ, foreign labeling and other regulatory actions do not bear—in this case—on the adequacy of Xarelto labeling or its design as approved by FDA for use in the United States. Defendants do not seek to exclude otherwise relevant scientific information generated outside the United States, evidence of otherwise relevant conduct of Defendants' non-United States employees, or otherwise relevant non-United States documents. Plaintiffs oppose the motion.

This evidence is likely excludable under Federal Rules of Evidence 401 and 403, but the Court will **RESERVE** its ruling on this issue because context or rebuttal use may have to be considered.

28) Defendants' OMNIBUS Motion in Limine No. 1 [R. Doc. 5955]

Defendants move to preclude Plaintiffs Joseph J. Boudreaux, Jr. and Loretta Boudreaux from presenting the following categories of evidence: (1) evidence and argument concerning Defendants' actual or anticipated profits from the sale of Xarelto; (2) evidence and argument concerning Defendants' overall sales, profitability, and market share; (3) evidence and argument relating to prescription medicine pricing; (4) evidence and argument concerning executive compensation; (5) evidence and argument concerning Adverse Event Reports as evidence of causation or notice, particularly in light attorney advertising that has artificially inflated and impacted AERs for Xarelto; (6) references to the presence, absence, or identity of a corporate representative at trial; and (7) evidence and argument concerning the moral or ethical, as opposed to legal, duties of pharmaceutical manufacturers. Plaintiffs oppose the motion.

The Court **SUSTAINS** this Motion, with the exception of the fifth category, "evidence and argument concerning Adverse Event Reports as evidence of causation or notice, particularly in light attorney advertising that has artificially inflated and impacted AERs for Xarelto," on which the Court **RESERVES** its ruling until trial.

29) Defendants' OMNIBUS Motion in Limine No. 2 [R. Doc. 5956]

Defendants move to preclude Plaintiffs Joseph J. Boudreaux, Jr. and Loretta Boudreaux from presenting the following categories of evidence: (1) Evidence and argument concerning the defense and indemnification provisions in the Collaborative Development and License Agreement; (2) Evidence and argument concerning Corporate Integrity Agreements, government investigations or settlements, and any other "bad acts" unrelated to Xarelto; (3) Evidence and

argument concerning Chameleon Communications or “ghostwriting” in connection with certain scientific articles; (4) Opinions from Plaintiffs’ expert witnesses that are beyond the scope of their Rule 26 expert reports; and (5) Evidence and argument concerning Defendants’ other litigation. Plaintiffs oppose the motion.

The Court **SUSTAINS** this Motion, with the exception of the categories two, three, and four, “evidence and argument concerning Corporate Integrity Agreements, government investigations or settlements, and any other ‘bad acts’ unrelated to Xarelto;” “evidence and argument concerning Chameleon Communications or ‘ghostwriting’ in connection with certain scientific articles;” and “opinions from Plaintiffs’ expert witnesses that are beyond the scope of their Rule 26 expert reports,” on which the Court **RESERVES** its ruling until trial.

30) Defendants’ JOINT Motion for an Order (1) Dismissing with Prejudice Claims Based on Allegations that Plaintiffs have Abandoned and (2) Barring Scientific Evidence Based on Waiver of Daubert Arguments [R. Doc. 5957]

Defendants move to (1) dismiss Plaintiffs’ causes of action to the extent they are based on abandoned allegation and (2) exclude scientific expert testimony pertaining to any abandoned allegation on the ground that Plaintiffs did not respond to Defendants’ Daubert challenges regarding those theories. Defendants contend that the briefs filed by Plaintiffs and their representations to the Court at oral argument of the parties’ dispositive and Daubert motions make it clear that Plaintiffs have expressly abandoned many of their original allegations. In particular, Defendants contend that Plaintiffs have abandoned their allegations (1) that Xarelto’s labeling should have included a “black box” warning regarding bleeding risk; (2) that Defendants failed to properly test Xarelto before bringing it to market; (3) that Xarelto’s once-daily dosing regimen is unreasonably dangerous; (4) that Xarelto’s 15 mg or 20 mg dose is too high; (5) that Xarelto’s labeling should have instructed physicians to monitor PT for the purpose of adjusting doses; (6) that Xarelto’s labeling should have instructed physicians to perform

routine monitoring of patients' PT; and (7) that Xarelto's labeling did not adequately warn of bleeding risk. Plaintiffs oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial.

31) Defendants' Motion in Limine Regarding the Record 4 Clinical Trial and SEIFE 2015 [R. Doc. 5958]

Defendants move to prevent Plaintiffs from introducing any evidence or argument regarding the RECORD 4 clinical trial or a 2015 article by journalist Charles Seife referencing the trial. They aver that the FDA did not consider the data collected in the RECORD 4 clinical trial in determining whether to approve Xarelto for the indication that was tested in the trial. Further, the RECORD clinical trials tested a different Xarelto dose, in a separate patient population, for an indication not at issue here. In addition to being irrelevant, evidence regarding RECORD 4 will unfairly prejudice Defendants, confuse the issues, and waste time. Allowing any such evidence would necessitate extensive testimony on the RECORD 4 clinical trial and the related regulatory history. The additional trial days that would have to be spent offering evidence on irrelevant and prejudicial clinical trial issues warrants exclusion. Plaintiffs oppose the motion.

The Court declines to rule on this motion at this time and will **RESERVE** its ruling for trial, finding that context and the Plaintiffs' use of the evidence may be relevant or dispositive.

CONCLUSION

For the aforementioned reasons, **IT IS ORDERED** that the following motions are **SUSTAINED**: R. Docs. 5919, 5921, 5923, 5925, 5926, 5927, 5929, 5930, 5933, 5937, and 5951.

IT IS FURTHER ORDERED that the Court's ruling on the following motions is **RESERVED** for trial: R. Docs. 5920, 5922, 5928, 5931, 5935, 5940, 5942, 5943, 5944, 5946, 5947, 5949, 5950, 5952, 5954, 5957, and 5958.

IT IS FURTHER ORDERED that the following motions are **SUSTAINED IN PART AND RESERVED IN PART**: R. Docs. 5924, 5955, and 5956.

New Orleans, Louisiana, this 18th day of April, 2017.


UNITED STATES DISTRICT JUDGE